FEB 2 8 2014

510(k) Summary

Nd: YAG Laser System
Beijing Toplaser Technology Co., Ltd.
(As required by 21 CFR 807.92)
K Number: K133158

1. Date Prepared: Sep. 22, 2013

2. Sponsor Information
Beijing Toplaser Technology Co., Ltd.
East 3rd Floor, Building M7, No.1 Jiuxianqiao East Road,
Chaoyang District, Beijing 100015, China
Contract Person: Zhang Xiaosong, General Manager
Phone: +86-10-64354759
Fax: +86-10-64356591

3. Proposed Device Information
Device Common or Usual Name: Nd: YAG Laser
Device Trade or Proprietary Name:
Qmetrx 1000 （Victory 11）Nd: YAG Laser System
Classification Name: Laser instrument, Surgical, Powered
Regulation Number: 21 CFR 878.481 0
Product Code: GEX
Panel: General and Plastic Surgery
Model: QMetrx1000 (Victory-11)

4. Predicate Device
Medlite C6 Q-Switched Nd：YAG Laser（K014234）
Medlite™ C³ Q-Switched Nd：YAG Laser（K011677）
Manufactured by Continuum Electro-Optics，Inc.

5. Device Description
The Nd: YAG Laser System is based on the Q-Switched Nd:YAG (1064 nm) and frequency doubled KTP Nd:YAG (532 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The frequency doubled KTP

Nd:YAG wavelength is achieved by directing the Nd:YAG laser beam through a frequency doubling non-linear crystal. The Nd:YAG laser is activated by means of the use of flashlamp. A red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided by articulated arm to a focusing handpiece.
Both laser wavelengths share a common power supply, control system, and cooling system. The internal microprocessor can be directed to select either the Nd:YAG or the KTP Nd:YAG laser wavelength. The physician is able to select the desired wavelength and the related output energy ,spot size ,fluence via control panel.

6. Intended use and Indications of Use

- Tattoo Removal
- Treatment of Vascular Lesions
- Treatment of Pigmented Lesions,
- Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

1064nm	532nm
Tattoo Removal ● Dark ink: blue and black	Tattoo Removal ● Light ink: red ● Light ink: sky blue and green
Treatment of Pigmented Lesions ● Nevus of ota	Treatment of Vascular Lesions ● Port wine birthmarks ● Telangiectasias ● Spider angioma ● Cherry angioma ● Spider nevi
	Treatment of Pigmented Lesions ● Café-au-lait birthmarks ● Solar lentiginos ● Senile lentiginos ● Becker's nevi ● Freckles ● Nevus spilus

7. Substantial Equivalence

The product Nd:YAG Laser System, model QMetrx1000(Victory-11) shares the similar indications for use, design features, functional features, same safety compliance. Therefore the product Nd:YAG Laser System, model

QMetrx1000(Victory-11) is substantially equivalent to its predicate device cited above without raising new safety and/or effectiveness issues.

8. Testing

The Nd: YAG Laser System is designed, tested and will be manufactured in accordance with both mandatory and voluntary standards, including:

- IEC 60825-1: Safety of laser products - Part 1: Equipment classification, requirements and user's guide.
- IEC 60601-2-22: Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for safety.
- IEC 60601-1-2: Medical Electrical Equipment -Part 1: General requirements for safety-2,Collateral Standard: Electromagnetic compatibility - Requirements and tests.
- UL 60601-1:2003 R6.03

Non-Clinical Conclusion:

Laboratory testing was conducted to validate and verify' that the proposed device, QMetrx1000(Victory-11) Nd: YAG Laser System met all design specifications and was substantially equivalent to the predicate device. No Clinical Information is required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Beijing Toplaser Techonology Company, Ltd.
Mr. Zhang Xiaosong
General Manager
East 3rd Floor, Building M7, No. 1 Jiuxianqiao East Road
Chaoyang District, Beijing 100015
CHINA

Re: K133158
Trade/Device Name: Qmetrx 1000 (Victory 11) Nd: YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 28, 2013
Received: December 2, 2013

Dear Mr. Xiaosong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K133158
Device Name: Qmetrx 1000 (Victory 11) Nd: YAG Laser System
Indications For Use:

- Tattoo Removal
- Treatment of Vascular Lesions
- Treatment of Pigmented Lesions,
- Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

1064nm	532nm
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Treatment of Pigmented Lesions • Nevus of ota	Treatment of Vascular Lesions • Port wine birthmarks • Telangiectasias • Spider angioma • Cherry angioma • Spider nevi
	Treatment of Pigmented Lesions • Café-au-lait birthmarks • Solar lentiginos • Senile lentiginos • Becker's nevi • Freckles • Nevus spilus

Prescription Use __YES__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of __1__

Felipe Aguel Date: 2014.02.28 14:20:51 -05'00'

(Division Sign-Off) for BSA
Division of Surgical Devices
510(k) Number ___K133158_____